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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,154	12/10/2001	Ryusuke Nakagiri	2139.27	2545

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EXAMINER	
DI NOLA BARON, LILIANA	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/010,154	NAKAGIRI ET AL.	
	Examiner	Art Unit	
	Liliana Di Nola-Baron	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6,16,24,30,31,37,38,43,44,49 and 50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6,16,24,30,31,37,38,43,44,49 and 50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Applicant's amendment, filed on January 22, 2004 is acknowledged.

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 30, 37, 43, 44 and 49 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 30, 37 and 49 read on compositions comprising an isolated Hydrangea, and claims 43 and 44 recite a method comprising feeding an animal with compositions comprising an isolated plant of the family Saxifragaceae. The isolated plant is found in nature and animals feed on plants from the family of Saxifragaceae. Birds, for example, open the berries of Gooseberry, Miccosukee of the Saxifragaceae family, to eat the seeds (See p. 10 in the article "Species Gooseberry, Miccosukee"). With respect to the form of the composition claimed in the instant application (food and drinks, feed, food and drink additive or feed additive), the leaves and fruits of the plants are natural forms of food, feed and food additives, and the juice in the fruit is a natural drink. Since Applicant does not claim any particular carrier, binder, homogenizing agent or any other conventional ingredient commonly used for the manufacture of food and drinks, feed, food additives and food additives, in the compositions and methods as claimed, hand labor or machinery are not required to produce compositions different from the natural plant. Consequently, the claims do not embody patentable subject matter as defined in 35 U.S.C. 101. MPEP 2105 provides several quotes from the Chakrabarty decision and summarizes: 5. "Thus, a new mineral discovered in the earth or a

new plant found in the wild is not patentable subject matter...". (See MPEP 2105, No. 5.). It is suggested that Applicant limits the invention to an extract isolated or purified from the plant to identify a product, which is not found in nature.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 6, 16, 24, 31, 38 and 50 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Regarding claims 6, 16, 24, 31, 38 and 50, it is not clear in the claims what is meant by "an extract of a residue obtained by extracting a plant of the family Saxifragaceae with an aqueous medium, in which the extract is obtained by extracting the residue with alcohol or water containing alcohol". The extract and the residue are not defined, and the claims are vague and confusing.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this

subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 6, 16, 24, 31, 38 and 50 are rejected under 35 U.S.C. 102(e) as being anticipated by Konishi (U.S. Patent 6,541,041).

The patent provides crude drug extracts obtained from Saxifraga stolonifera (See col. 3, lines 31-54), and teaches that pure water and ethanol are added to a crude plant extract (See col. 4, lines 18-23), as claimed in instant claims 6, 16, 24, 31, 38 and 50. The patent teaches that the extract can be made into solid or liquid pharmaceutical preparations for oral administration for treating animals and humans, and includes tablets, capsules, powders and liquids among the formulations for oral administration (See col. 6, lines 13-32). The powders, tablets, capsules and liquids provided by the prior art are forms of drink and food or feed, as claimed by Applicant. With regard to the additive for foods and drinks claimed in claim 31, and the feed additive claimed in claim 38, the tablets, capsules, powders and liquids disclosed by the prior art are supplements, and the patent teaches that the extracts are used for treating both animals and humans (See col. 6, lines 30-32), thus the patent contemplates food and feed additives, as claimed by Applicant. The compositions disclosed by Konishi meet the limitations of claims 6, 16, 24, 31, 38 and 50 of the instant application, as they contemplate oral compositions comprising an extract of Saxifraga stolonifera, a plant of the family Saxifragaceae, as claimed by Applicant. Thus, the patent anticipates the claimed invention.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 30, 37, 43, 44 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamahara et al. (XP002220391) in view of Levinson et al. (U.S. Patent 6,479,545).

Yamahara et al. provides methanol extracts of Hydrangea Dulcis Folium, and teaches that the extract has cholagoic (bile-related) activity (See Introduction and p. 1). Thus, the paper provides the teachings that extracts of the species Hydrangea Dulcis Folium are known in the art and beneficially affect liver functions. The paper is deficient in the sense, that it is silent with respect to administering the plant extract to a subject, as claimed in claims 43 and 44, and does not provide dosage forms of the extract for oral administration, as claimed in claims 30, 37 and 49 of the instant application.

Levinson et al. provides compositions comprising herbals and herbal derivatives, such as herbal extracts and substances derived from plants and plant parts, such as leaves, flowers and roots, including Hydrangea (See col. 13, line 66 to col. 14, line 59). Levinson et al. teaches that the compositions of the invention may be in the form of tablets, powders, elixirs, liquids, as well as in the form of animal feeds, cereals, cereal coatings, yogurts and foods, and the nutritional compositions may be administered orally (See col. 16, line 7 to col. 17, line 23), thus the patent

contemplates oral administration of the compositions, and provides the teachings that compositions comprising an extract of hydrangea may be administered orally to humans and animals in the form of foods, drinks, feed, food additives and feed additives (See col. 14, lines 22-58 and col. 16, line 7 to col. 17, line 35).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the extract of Hydrangea Dulcis Folium disclosed by Yamahara et al. in the form of food, drink and feed, as claimed in claim 49, additive for foods and drinks, as claimed in claim 30, and feed additive, as claimed in claim 37, as taught by Levinson et al., and to devise a method comprising feeding an animal with the compositions of the invention, as claimed in claims 43 and 44, to improve liver functions, as taught by Yamahara et al. The expected result would have been a successful oral nutritional composition of the extract of Hydrangea Dulcis Folium and a successful method for protecting or improving a liver function. Because of the teachings of Yamahara et al., that extracts of Hydrangea Dulcis Folium are known in the art and beneficially affect liver functions, and the teachings of Levinson et al., that compositions comprising an extract of hydrangea may be administered orally to humans and animals in the form of foods, drinks, feed, food additives and feed additives, one of ordinary skill in the art would have a reasonable expectation that the compositions and methods claimed in the instant application would be successful in providing nutritional compositions, which are edible to humans and animals, and a non-aggressive method of protecting or improving liver functions. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

10. Claims 6, 16, 24, 31, 38, 43 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuji Rebio (XP002220392) in view of Konishi (U.S. Patent 6,541,041). Fuji Rebio discloses tannins purified from Saxifraga stolonifera and teaches that the tannins can be applied to the treatment of hepatitis B (a viral disease of the liver) in admixture with proper vehicles, including fillers and bulking agents, in the form of tablet, powder, granules and pill for oral administration (See Abstract). Thus, the paper provides the teachings that substances isolated from Saxifraga stolonifera may be used in oral dosage forms for the treatment of a liver disease. With regard to claims 6, 16, 24, 31, 38 and 44, the patent is deficient in the fact , that it does not specify how the plant extract is processed. With respect to claims 43 and 44 of the instant application, Fuji Rebio is deficient in the sense, that it does not specifically teach that the compositions are administered to an animal.

Konishi provides crude drug extracts of Saxifraga stolonifera and teaches that water, ethanol or a mixed solution thereof is used as an extracting solvent (See col. 5, lines 4-51).
With respect to the step of feeding an animal with a plant extract, which is recited in the method claimed in claims 43 and 44 of the instant application, Konishi teaches that the plant extract can be made into solid or liquid pharmaceutical preparations for oral administration for treating animals and humans, and includes tablets, capsules, powders and liquids among the formulations for oral administration (See col. 6, lines 13-32).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide extracts of saxifraga stolonifera using water and ethanol as

extracting solvents, as taught by Konishi, and to devise a method comprising feeding an animal with compositions comprising extracts of Saxifraga stolonifera, as claimed in claims 43-44, to improve liver functions, by treating disorders caused by the hepatitis B virus, as taught by Fuji Rebio. The expected result would have been a successful oral composition of the extract of Saxifraga stolonifera and a successful method for protecting or improving a liver function. Because of the teachings of Fuji Rebio, that agents in the extracts of Saxifraga stolonifera are effective against the hepatitis B virus and thus beneficially affect liver functions, and the teachings of Konishi, that compositions comprising an extract of Saxifraga stolonifera are obtained by water and alcohol extraction and may be administered orally to humans and animals, one of ordinary skill in the art would have a reasonable expectation that the compositions and methods claimed in the instant application would be successful in providing nutritional compositions, which are edible to humans and animals, and a non-aggressive method of protecting or improving liver functions. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

11. Applicant's arguments filed on January 22, 2004 have been fully considered but they are not persuasive.

12. Applicant argues that Yamahara does not disclose the species of Hydrangea Dulcis Folium. In response to said argument, it is noted that the prior art provides extracts of Hydrangea Dulcis Folium (See Introduction, p. 1).

13. In response to Applicant's argument, that Fuji Rebio does not teach a method for obtaining the tannins, it is noted that the examiner relies on Konishi for the teachings that plants from the family of Saxifragaceae may be extracted with water and alcohol.

14. In reply to Applicant's argument, that Konishi does not teach a two-step extraction method, it is noted that such a method is not claimed in the newly amended claims by Applicant.

15. In response to Applicant's argument, that Example 2 is representative of Konishi, it is noted that examples in the prior art are the inventor's best mode. It is not necessary for the prior art to disclose Applicant's invention in the best mode, as long as the prior art provides the teachings that plants from the family of Saxifragaceae can be extracted with water and alcohol.

Conclusion

16. Claims 6, 16, 24, 30, 31, 37, 38, 43, 44, 49 and 50 are rejected.

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liliana Di Nola-Baron whose telephone number is 571-272-0592. The examiner can normally be reached on Monday through Thursday, 8:30AM-7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LDNB

May 6, 2004

THURMAN K PAGE
SUPERVISORY PATENT EXAMINER
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